Attorney Docket No.: 10123/03203

REMARKS

Claims 56, 59-66, 68-72 and 74-81 are pending in this application. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

The Examiner asserts that the drawings should be amended to show a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end, stating that Figs. 1 and 3 do not show what is claimed. However, it is respectfully submitted that this is clearly shown in amended Fig. 7 which was filed with the Response under Rule 116 dated February 23, 2006. This response was entered as indicated by the Advisory Action mailed March 22, 2006. Amended Fig. 7 shows a catheter 26 including first and second lumens 20 and 24 extending therethrough from a proximal end at hubs 38 of the Y-adapter to a distal end within a vessel 22. Furthermore, it is noted that the Y-adapter is a unitary element comprising a single proximal end including two hubs 38. Thus, Applicants respectfully request that the Examiner withdraw the objection to the drawings.

Claim 56 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. In view of the amendment to Fig. 7 and the above remarks, it is respectfully requested that this rejection be withdrawn.

Claims 56, 59-66, 68-69 and 80 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,158,540 to Wijay et al. ("Wijay").

Claim 56 recites a system for establishing intermittent fluid communication with a patient's bloodstream comprising "a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient" in combination with "*a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*" and "a deflation mechanism for deflating the first balloon to reopen the first lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel."

In contrast, Wijay discloses an angioplasty perfusion catheter which is insertable through a separate guiding catheter. The Examiner notes that the Wijay device contains a balloon 16 in the annular passage 30. However, it is noted that the balloon 16 is not located at "a distal end of the first lumen to prevent blood flow thereinto", as recited in claim 56. Rather, the proximal balloon 16 is positioned along a length of the annular passage 30 to seal off the annular passage 30 for distal hemoperfusion. (*See* Wijay, col. 4, ll. 16-19; FIG. 1). It is noted that the positioning of the balloon 16 in the Wijay device allows blood and other fluid to enter the annular passage 30. Specifically, the balloon 16 is designed only to prevent blood from flowing distally therepast. That is, when blood in pumped into the annular space 30, the balloon 16 prevents this blood from flowing out of the annular space 30 into the portion of the artery proximal to the balloon 17. This blood is then forced into the lumen 26 via holes 15 so that it may enter the artery distal to the balloon 17, maintaining blood flow through the artery. (*See* Wijay, col. 4, ll. 19-26). Thus, the balloon 16 is positioned immediately distal to the openings 15 and the balloon 16 is not designed to prevent blood from flowing into the distal portion of the annular space 30, nor is the balloon 16 suitable for this purpose. It is therefore noted that Wijay does not teach or suggest "*a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*", as recited in claim 56.

Furthermore, it is noted that the second sealing balloon 17 of the Wijay device also does not cure the deficiencies of the first balloon 16. Specifically, it is noted that the balloon 17 is not "positionable within a distal end of the first lumen", as recited in claim 56. Rather, the device is operable only when the balloon 17 is inflated in the artery at the stenosis. (*See* Wijay, col. 4, ll. 13-16). It is therefore noted that the Wijay device is not directed to teaching a catheter including any structure for preventing blood flow into the distal end thereof, as recited in claim 56. Additionally , it is noted that to employ a sealing balloon that seals a distal end of the first lumen to prevent blood flow thereinto, as recited in claim 1, would be detrimental to the Wijay device, which is directed to maintaining fluid communication between the catheter and the lumen of the patient. (*See* Wijay, col. 2, ll. 55-59).

It is submitted that Wijay neither teaches nor suggests "*a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*", as recited in claim 56 and that

claim 56 is allowable for at least this reason.

Claim 59 recites limitations substantially similar to those of claim 56 including "inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen." Thus, it is respectfully submitted that claim 59 is allowable for at least the same reasons as claim 56. Because claim 60-63 depend from, and therefore, include all of the limitations of claim 59, it is respectfully submitted that these claims are also allowable.

Claim 64 recites limitations substantially similar to those of claim 56 including "inflating a balloon to seal the hollow interior passageway at a distal end of the catheter to prevent blood in the vessel from entering the hollow interior passageway." Thus, it is respectfully submitted that claim 64 is allowable for at least the same reasons as claim 56.

Claim 65 recites limitations substantially similar to those of claim 56 including "a balloon which, when inflated, physically contacts and seals the distal end of the lumen to prevent blood flow thereinto." Thus, it is respectfully submitted that claim 65 is allowable for at least the same reasons as claim 56. Because claims 66 and 68-69 depend from, and, therefore include all of the limitations of claim 65, it is respectfully submitted that these claims are also allowable.

Claim 80 recites limitations substantially similar to those of claim 56 including "sealing the first lumen to discontinue fluid communication with the bodily fluid by: advancing a first deflated balloon along the first lumen to position at least partially radially within a distal end thereof; and inflating the first balloon to seal the first lumen at the distal end thereof." Thus, it is respectfully submitted that claim 80 is allowable for at least the same reasons as claim 56.

Claims 56, 59-66, 68-69 and 80 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,771,777 to Horzewski et al. ("Horzewski").

The Horzewski device is directed toward a perfusion-type dilation apparatus to regulate the flow of blood pumped into a stenosis. It is noted that Horzewski does not teach or suggest "a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient" in combination with "a first sealing balloon

positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto" and "a deflation mechanism for deflating the first balloon to reopen the first lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel", as recited in claim 56.

The Examiner references tubular member 14 and balloon 82 of the Horzewski device in support of this rejection. It is noted that the balloon 82 is situated on a distal end of the tubular member 14, which contains only the lumen 18. (*See* Horzewski, col. 2, ll. 28-30). Claim 56, on the other hand, recites the employment of "a catheter including *first and second* lumens extending therethrough." Horzewski teaches only one lumen extending therethrough from a proximal to a distal end. It is submitted that the tubular membrane 77, which contains at least one lumen does not share proximal and distal ends with the tubular member 14 and therefore does not teach the limitations of claim 56. (*See* Horzewski, FIG. 9). It is therefore noted that Horzewski does not teach or suggest "*a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof*, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient," as recited in claim 56.

Furthermore, Horzewski teaches a balloon 82 which is situated along the tubular membrane 77 which contains a plurality of openings 92 and circumferentially placed holes 93. (*See* Horzewski, col. 5, line 65 – col. 6, line 12; FIG. 9). These openings are designed to allow blood to travel to/from the stenosis even during inflation, so as to avoid a situation where blood flow is temporarily blocked between the catheter and the stenosis. Specifically, Horzewski notes that "[b]lood therefore flows through the dilatation catheter into a region beyond the stenosis so that there is a continued supply of blood to the heart muscle during the period of inflation of the balloon." (*Horzewski*, col, 7, ll. 22-28). It is therefore noted that Horzewski does not teach or suggest a catheter that may "seal[s] the distal end of the first lumen to prevent blood flow thereinto", as recited in claim 56. Rather, Horzewski deliberately tries to overcome a situation where blood flow would be blocked by introducing the plurality of openings 92 and circumferentially placed holes 93 into the design. Additionally, it is noted that the employment of a design that "seals a distal end of the first lumen to prevent blood flow thereinto", as recited in claim 56, would be detrimental to the Horzewski device, which is reliant on constant fluid communication between the catheter and the stenosis of the artery. (*Id.*).

It is therefore noted that Horzewski fails to teach or suggest "a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, *the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*" and "a deflation mechanism for deflating the first balloon *to reopen the first lumen to blood flow thereinto* while the distal end of the catheter remains within the blood vessel", as recited in claim 56. It is respectfully submitted that claim 56 is allowable for at least this additional reason.

Claim 59 recites substantially similar limitations as claim 56 including "inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen" and "purging the first lumen." Thus, it is respectfully submitted that claim 59 is allowable for at least the same reasons as claim 56. Because claim 60-63 depend from, and therefore, include all of the limitations of claim 59, it is respectfully submitted that these claims are also allowable.

Claim 64 recites limitations substantially similar to those of claim 56 including *"inflating a balloon to seal the hollow interior passageway* at a distal end of the catheter to prevent blood in the vessel from entering the hollow interior passageway" and *"deflating the previously inflated balloon to unseal the hollow interior passageway* when flow through the hollow interior passageway is desired."Thus, it is respectfully submitted that claim 64 is allowable for at least the same reasons as claim 56.

Claim 65 recites limitations substantially similar to those of claim 56 including "a balloon which, when inflated, physically contacts and seals the distal end of the lumen to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel." Thus, it is respectfully submitted that claim 65 is allowable for at least the same reasons as claim 56. Because claims 66 and 68-69 depend from, and, therefore include all of the limitations of claim 65, it is respectfully submitted that these claims are also allowable.

Claim 80 recites limitations substantially similar to those of claim 56 including "sealing the first lumen to discontinue fluid communication with the bodily fluid by: advancing a first deflated balloon along the first lumen to position at least partially radially within a distal end

thereof; and inflating the first balloon to seal the first lumen at the distal end thereof" and "reestablishing fluid communication with the bodily fluid by deflating the first balloon to initiate a second treatment session." Thus, it is respectfully submitted that claim 80 is allowable for at least the same reasons as claim 56.

Claims 56, 59-66, 68-69 and 80 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,867,742 to Calderon ("Calderon").

The Examiner has analogized the balloon 56 of the Calderon device to the first sealing balloon disclosed in claim 56. However, it is noted that the balloon 56 of the Calderon device is positioned along the outer circumference of the distal end of the suction lumen 52. (*See* Calderon, Figs. 2, 3) and in no way controls the flow of fluids into an internal lumen of the device. Specifically, the balloon 56 is "inflatable in the patient's vein via a port *to seal the vein*, blocking the flow of infused fluids from the injection lumen 18 to the remainder of the patient's body." (*Calderon*, col. 6, ll. 47-51). That is, the balloon of Calderon controls the flow of fluids injected into a patient by preventing these fluids from passing around the outside of the catheter to undesired parts of the body, and does not "seal the distal end of the first lumen to prevent blood flow thereinto", as recited in claim 56. The balloon 52 is external to the catheter lumen and only seals against the periphery of the vein while leaving the lumen itself open to fluid flow. Consequently, it is also respectfully submitted that Calderon does not teach a device whereby the balloon may be deflated "to reopen the first lumen to blood flow thereinto," as recited in claim 56.

It is therefore noted that Calderon fails to teach or suggest "a catheter including first and second lumens *extending therethrough from a proximal end of the catheter to a distal end thereof*, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient" in combination with "*a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*" and "a deflation mechanism for *deflating the first balloon to reopen the first lumen to blood flow thereinto* while the distal end of the catheter remains within the blood vessel", as recited in claim 56 and that claim 56 is allowable for at least the reasons noted above.

Claim 59 recites limitations substantially similar to those of claim 56 including "inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen" and "purging the first lumen." Thus, it is respectfully submitted that claim 59 is allowable for at least the same reasons as claim 56. Because claim 60-63 depend from, and therefore, include all of the limitations of claim 59, it is respectfully submitted that these claims are also allowable.

Claim 64 recites limitations substantially similar to those of claim 56 including *"inflating a balloon to seal the hollow interior passageway* at a distal end of the catheter *to prevent blood in the vessel from entering the hollow interior passageway*" and *"deflating the previously inflated balloon to unseal the hollow interior passageway* when flow through the hollow interior passageway is desired."Thus, it is respectfully submitted that claim 64 is allowable for at least the same reasons as claim 56.

Claim 65 recites limitations substantially similar to those of claim 56 including "a balloon which, when inflated, physically contacts and seals the distal end of the lumen *to prevent blood flow thereinto*" and "a deflation mechanism for *deflating the balloon to reopen the lumen to blood flow thereinto* while the distal end of the catheter remains within the blood vessel." Thus, it is respectfully submitted that claim 65 is allowable for at least the same reasons as claim 56. Because claims 66 and 68-69 depend from, and, therefore include all of the limitations of claim 65, it is respectfully submitted that these claims are also allowable.

Claim 80 recites limitations substantially similar to those of claim 56 including "*sealing the first lumen to discontinue fluid communication with the bodily fluid* by: advancing a first deflated balloon along the first lumen to position at least partially radially within a distal end thereof; and *inflating the first balloon to seal the first lumen at the distal end thereof*" and "*reestablishing fluid communication with the bodily fluid by deflating the first balloon* to initiate a second treatment session." Thus, it is respectfully submitted that claim 80 is allowable for at least the same reasons as claim 56.

Claims 56, 59-66, 68-69 and 80 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,403,274 to Cannon ("Cannon").

The Cannon device is directed to a catheter for pressure equalization of fluids traveling between the catheter and a blood vessel. (*See* Cannon, col. 2, line 64 – col. 3, line 1). Specifically, the Cannon device contains a balloon 44 located along a distal end of a guide catheter 12, the balloon 44 being distal to a port 32 and at least one opening 48 located along the guide catheter 12. (*See* Cannon, col. 3, ll. 7-11). Cannon states that the "guide catheter 12 may have more than one opening to enable fluid communication between the blood vessel BB and the guide lumen 18." (*Cannon*, col. 5, ll. 11-14). In light of the above, it is noted that the balloon 44 of the Cannon device is not designated to "seal the distal end of the first lumen to prevent blood flow thereinto," as recited in claim 56. Rather, the balloon 44 is employed to equalize pressure inside the catheter and within the vessel while permitting fluid flow between the vessel and the catheter lumen, so that a physician may apply a regulated amount of pressure to the blood vessel being infused. (*See* Cannon, col. 6, ll. 3-10). The port 32 and at least one opening 48 of the Cannon device ensure that, even with the balloon 44 inflated, the injection port is always in fluid communication with the blood vessel. Thus, it is respectfully submitted that, not only does Cannon show no sealing of its catheter lumen as claimed, in fact it teaches away from such a modification as a sealed end would prevent the performance of its intended function -- i.e., applying "pressure (a predetermined amount) to the plunger 62 to force fluid into the guide lumen 18 to initiate flow from the blood vessel, into the opening 48, into the port 32m through the first balloon lumen, past the inflated balloon 44 and the inflated distal balloon 22, and out the opening 34 at the distal end 24 of the balloon catheter 20." (*See* Cannon, col. 6, ll. 3-10).

It is therefore submitted that Cannon does not teach or suggest "*a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof*, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient" in combination with "a first sealing balloon positionable within a distal end of the first lumen, so that, *when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*" and "a deflation mechanism for *deflating the first balloon to reopen the first lumen to blood flow thereinto* while the distal end of the catheter remains within the blood vessel," as recited in claim 56 and that claim 56 is allowable over Cannon.

Claim 59 recites limitations substantially similar to those of claim 56 including "inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen" and "purging the first lumen." Thus, it is respectfully submitted that

claim 59 is allowable for at least the same reasons as claim 56. Because claim 60-63 depend from, and therefore, include all of the limitations of claim 59, it is respectfully submitted that these claims are also allowable.

Claim 64 recites limitations substantially similar to those of claim 56 including *"inflating a balloon to seal the hollow interior passageway* at a distal end of the catheter *to prevent blood in the vessel from entering the hollow interior passageway*" and *"deflating the previously inflated balloon to unseal the hollow interior passageway* when flow through the hollow interior passageway is desired." Thus, it is respectfully submitted that claim 64 is allowable for at least the same reasons as claim 56.

Claim 65 recites substantially similar limitations as claim 56 including "a balloon which, when inflated, physically contacts and seals the distal end of the lumen *to prevent blood flow thereinto*" and "a deflation mechanism for *deflating the balloon to reopen the lumen to blood flow thereinto* while the distal end of the catheter remains within the blood vessel." Thus, it is respectfully submitted that claim 65 is allowable for at least the same reasons as claim 56. Because claims 66 and 68-69 depend from, and, therefore include all of the limitations of claim 65, it is respectfully submitted that these claims are also allowable.

Claim 80 recites limitations substantially similar to those of claim 56 including "*sealing the first lumen to discontinue fluid communication with the bodily fluid* by: advancing a first deflated balloon along the first lumen to position at least partially radially within a distal end thereof; and *inflating the first balloon to seal the first lumen at the distal end thereof*" and "*reestablishing fluid communication with the bodily fluid by deflating the first balloon* to initiate a second treatment session." Thus, it is respectfully submitted that claim 80 is allowable for at least the same reasons as claim 56.

Claims 59-64 stand rejected under 35 U.S.C. § 103(a) as obvious over Wijay in view of U.S. Patent No. 5,176,698 to Burns et al. ("Burns").

As stated above, Wijay neither discloses nor suggests "inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen", as recited in claim 59. It is respectfully submitted that Burns does not cure the

deficiencies of Wijay. Specifically, a balloon member 16 in Burns is disposed circumferentially around a distal end opening 47 of a shaft 14 and never seals/opens the distal end opening 47. In fact, the distal end opening 47 is permanently sealed to prevent proximal flow therethrough, only allowing gas from inside the shaft 14 to be expelled from therefrom. Thus, it is respectfully submitted that neither Wijay nor Burns, either alone or in combination, discloses or suggests "inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen," as recited in claim 59. Because claims 60-63 depend from, and, therefore include all of the limitations of claim 59, it is respectfully submitted that these claims are also allowable.

Claim 64 recites limitations substantially similar to those of 59 including "inflating a balloon to seal the hollow interior passageway at a distal end of the catheter to prevent blood in the vessel from entering the hollow interior passageway." Therefore, at least for the reasons described above with respect to claim 59, it is respectfully submitted that claim 64 is also allowable.

Claims 70-72, 74-79 and 81 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Wijay or alternatively Horzewski or alternatively Calderon or alternatively Cannon.

Claim 70 recites a system for establishing intermittent fluid communication with a patient's bloodstream comprising "first and second non-concentric catheters each of the first and second catheters including a lumen extending therethrough between proximal and distal ends thereof, wherein, when in an operative position, the distal ends of the first a and second catheters reside within a blood vessel of a patient" in combination with "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel."

Wijay fails to teach or suggest "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood

flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel." Rather, Wijay discloses a balloon 16 in the annular passage 30, which is not located at a distal end of the lumen to prevent blood flow thereinto, as noted in claim 70. Rather, the proximal balloon 16 is positioned along a length of the annular passage 30 to seal off the annular passage 30 for distal hemoperfusion. (*See* Wijay, col. 4, ll. 16-19; FIG. 1). It is noted that the positioning of the balloon 16 in the Wijay device would allow blood and other fluid to enter the annular passage 30. It is therefore noted that Wijay does not teach or suggest "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto," as recited in claim 70.

Furthermore, it is noted that the second sealing balloon 17 of the Wijay device also does not cure the deficiencies of the first balloon 16. Specifically, it is noted that the balloon 17 is not positionable within a distal end of the lumen, as noted in claim 70. Rather, the balloon 17 is situated and inflated in the stenosis. (*See* Wijay, col. 4, ll. 13-16). It is therefore noted that the Wijay device is not directed to teaching a catheter that may effectively position a sealing balloon to prevent blood flow into the catheter, as noted in claim 70. It is therefore noted that Wijay does not teach or suggest the limitations of claim 70 and claim 70 is allowable over Wijay. Because claims 71, 72 and 74 depend from and include all of the limitations of claim 70, it is respectfully submitted that these claims are also allowable.

Claims 75-79 depend from, and therefore, include all the limitations of claim 59. As noted above, claim 59 is allowable over Wijay. It is therefore submitted that claims 75-79 are also allowable. Claim 81 depends from, and therefore includes all the limitations of claim 56, which, as noted above, is also allowable over Wijay. It is therefore submitted that claim 81 is allowable.

Horzewski also fails to teach or suggest "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood

vessel", as recited in claim 70.

As noted above, Horzewski teaches a balloon 82 which is situated along the tubular membrane 77 which contains a plurality of openings 92 and circumferentially placed holes 93. (*See* Horzewski, col. 5, line 65 – col. 6, line 12; Fig. 9). These openings are designed to allow blood to travel to/from the stenosis even during inflation, so as to avoid a situation where blood flow is temporarily blocked between the catheter and the stenosis. Specifically, Horzewski notes that "[b]lood therefore flows through the dilatation catheter into a region beyond the stenosis so that there is a continued supply of blood to the heart muscle during the period of inflation of the balloon." (*Horzewski*, col. 7, ll. 22-28). It is therefore noted that Horzewski does not teach or suggest a catheter that may "seal[s] the distal end of the first lumen to prevent blood flow thereinto", as recited in claim 56. Rather, Horzewski deliberately tries to overcome a situation where blood flow would be blocked by introducing the plurality of openings 92 and circumferentially placed holes 93 into the design.

It is therefore noted that Horzewski fails to teach or suggest the limitations of claim 70 and that claim 70 is allowable. Because claims 71, 72 and 74 depend from and include all of the limitations of claim 70, it is respectfully submitted that these claims are also allowable.

Claims 75-79 depend from, and therefore, include all the limitations of claim 59. As noted above, claim 59 is allowable over Horzewski. It is therefore submitted that claims 75-79 are also allowable. Claim 81 depends from, and therefore includes all the limitations of claim 56, which, as noted above, is also allowable over Horzewski. It is therefore submitted that claim 81 is allowable.

Calderon also fails to teach or suggest "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel", as recited in claim 70.

As noted above, the balloon 56 of the Calderon device is located along the outer

circumference of the distal end of the suction lumen 52. (*See* Calderon, FIGS. 2,3). The balloon 56 is "inflatable in the patient's vein via a port to deal the vein, blocking the flow of infused fluids from the injection lumen 18 to the remainder of the patient's body." (*Calderon*, col. 6, ll. 47-51). It is therefore noted that the balloon of the Calderon device is intended to prevent infusion fluid from passing around the outside of the catheter to certain portions of the anatomy and not to "seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto," as recited in claim 70. Furthermore, Calderon does not teach a device whereby the balloon may be deflated "to reopen the lumen to blood flow thereinto", as recited in claim 70.

It is therefore noted that Calderon fails to teach or suggest the limitations of claim 70 and that claim 70 is allowable. Because claims 71, 72 and 74 depend from and include all of the limitations of claim 70, it is respectfully submitted that these claims are also allowable.

Claims 75-79 depend from, and therefore, include all the limitations of claim 59. As noted above, claim 59 is allowable over Calderon. It is therefore submitted that claims 75-79 are also allowable. Claim 81 depends from, and therefore includes all the limitations of claim 56, which, as noted above, is also allowable over Calderon. It is therefore submitted that claim 81 is allowable.

Cannon also fails to teach or suggest "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel", as recited in claim 70.

As noted above, the Cannon device contains a balloon 44 located along a distal end of a guide catheter 12, the balloon 44 being distal to a port 32 and at lease one opening 48 located along the guide catheter 12. (*See* Cannon, col. 3, ll. 7-11). Cannon goes on to state that the "guide catheter 12 may have more than one opening to enable fluid communication between the blood vessel BB and the guide lumen 18."(*Cannon*, col. 5, ll. 11-14). In light of the above, it is noted that the balloon 44 of the Cannon device is not designated to "seal the respective distal

ends of the lumens of the first and second catheters to prevent blood flow thereinto", as recited in claim 70. Rather, the balloon 44 is employed to equalize the pressure level inside the catheter, so that a physician may apply a regulated amount of pressure to the blood vessel being infused. (*See* Cannon, col. 6, ll. 3-10). The port 32 and at lease one opening 48 of the Cannon device ensure that, even with the balloon 44 inflated, the injection port is always in fluid communication with the blood vessel.

It is therefore noted that Cannon fails to teach or suggest the limitations of claim 70 and that claim 70 is allowable. Because claims 71, 72 and 74 depend from and include all of the limitations of claim 70, it is respectfully submitted that these claims are also allowable.

Claims 75-79 depend from, and therefore, include all the limitations of claim 59. As noted above, claim 59 is allowable over Cannon. It is therefore submitted that claims 75-79 are also allowable. Claim 81 depends from, and therefore includes all the limitations of claim 56, which, as noted above, is also allowable over Cannon. It is therefore submitted that claim 81 is allowable.

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CONCLUSION

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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